

Application No.: 09/680465 Case No.: 48317US028

REMARKS

Claims 67-80 have been added to this application. Thus, claims 33, 35-58, 60-64, and 66-80 are now pending in this application. Claim 33 has been amended to improve its wording.

Claims 33, 35-57, 59-63, 65, and 66 have been noted to conflict with a number of claims in applicants' copending patent applications. The Examiner has not, however, identified the particular conflict. To the extent, however, that the Examiner can establish that applicants are claiming the same invention or an invention that would have been obvious in view of the claims present in any of those copending applications, applicants will either cancel those claims or file a terminal disclaimer to overcome any double patenting rejection that may exist in this case when it is otherwise in condition for allowance.

Claims 33, 35-46, 48-57, and 59 have been rejected under 35 USC § 103(a) as being unpatentable over UK Patent 2,072,516 to Simpson. Applicants respectfully submit that this rejection cannot be sustained.

Applicants' invention pertains to a filtering face mask 10 that comprises a mask body 12 that is adapted to fit over the nose and mouth of a wearer. The filtering face mask 10 also has an exhalation valve 14 that is attached to the mask body 10. The exhalation valve comprises a valve seat 26 and a single flexible flap 24. The valve seat 26 includes a seal surface 31 and an orifice 32. The flexible flap 24 has a stationary or fixed portion 28 and only one free portion. The stationary portion 28 remains at rest during an exhalation, and the free portion is lifted away from the seal surface 31 during an exhalation. The free portion is located below the stationary portion when the filtering face mask is worn on a person. A valve of this type of construction is commonly referred to as a flapper valve, as opposed to the commonly used button-style valves (see, for example, Figure 3 of Simpson), which have the whole peripheral edge of the flap free to be lifted from the valve seat. In applicants' flapper valve, the flexible flap would normally assume a flat configuration when no forces are applied to it, but the flap has a curved profile when viewed from the side in its secured position on the valve seat and is pressed towards the seal surface 31 in an abutting relationship with it when a fluid is not passing through the orifice.

The Simpson disclosure would not have rendered applicants' invention obvious to a person of ordinary skill for the following reasons.

11PC 220

Application No.: 09/680465 Case No.: 48317US028

Firstly, Simpson does not teach or suggest a flap that is normally flat but is curved in its secured position on the exhalation valve when a fluid is not passing through the orifice. Simpson's valve 13 of Figure 2 has a slight curvature imparted to it, but this view is probably taken as a "snapshot" when a fluid is passing through the orifice. Otherwise, the flap would be disposed in a planar or flat configuration. If, however, Simpson's flap is pre-curved — that is, it takes on the configuration shown in Figure 2 when a fluid is not passing through the orifice — then Simpson fails to show a flap that would normally be flat. Under either circumstance, Simpson's disclosure does not reveal this feature of the present invention. The mere showing of a curved flap in the drawing, absent anything else, does not amount to a description sufficient to render an invention obvious under the terms of 35 USC § 103.1

Secondly, Simpson fails to teach or suggest a flexible flap that is pressed towards a seal surface when a fluid is not passing through the orifice. Simpson does not indicate that the flap 15 in Figure 2 is pressed against the seal surface. Simpson's flap 15 should reside in a perfectly linear configuration when at rest, and there is nothing in the text that suggests that it is otherwise biased towards the seal surface. Flap 15 would appear to be in nothing more than mere contact with the valve seat under neutral conditions.

An expert in the field of respirators and respirator components, David M. Castiglione, in his February 2, 2001 Affidavit, has provided evidence that establishes that the valve 13 shown in Figure 2 of Simpson does not have its flap 15 pressed in an abutting relationship towards the seal

See, In re Meng, 181 USPQ 95, 97 (CCPA 1974) ("We are aware, of course, that a claimed invention may be anticipated or rendered obvious by a drawing in a reference, whether the drawing disclosure be accidental or intentional. But, as the solicitor correctly states, a drawing is available as a reference for all that it teaches a person of ordinary skill in the art. The drawing here, Figure 10 of Beck, simply would not, in our view, teach or suggest the claimed invention to those who had never seen appellants' disclosure." (citation omitted)); In re Legrice, 133 USPQ 365, 372 (CCPA 1962) ("We think it is sound law, consistent with the public policy underlying our patent law, that before any publication can amount to a statutory bar to the grant of a patent, its disclosure must be such that a skilled artisan could take its teachings in combination with his own knowledge of the particular art and be in possession of the invention."); In re Turlay, 134 USPQ 355, 360 (CCPA 1962) ("The preceding discussion all adds up to the fact that we cannot, with any degree of certainty, ascertain whether Moseley discloses one or two exhaust valves in each bank communicating with the transverse passage. Under these circumstances we cannot agree with the majority of the board that Moseley anticipates applicant's appealed claim."); and, In re Wright, 193 USPQ 332, 335 (CCPA 1977) ("We disagree with the Solicitor's conclusion, reached by a comparison of the relative dimensions of appellant's and Bauer's drawing figures, that Bauer clearly points to the use of a chime length of roughly 1/2 to 1 inch for a whiskey barrel. This ignores the fact that Bauer does not disclose that his drawings are to scale. Absent any written description in the specification of quantitative values, arguments based on measurement of a drawing are of little value.").

Case No.: 48317US028

surface when a wearer is neither inhaling nor exhaling. Castiglione states that "there is nothing that can be discerned from Figure 2 or from the specification that would indicate that the flap is pressed towards the seal surface in its neutral position." Another expert in the field of exhalation valves, John Bowers, has similarly stated:

My review of the Simpson document reveals a flapper-style valve 13 in Fig. 2, which would not have its "flexible circular flap member 15" pressed against the valve's seal surface when a wearer of the mask is neither inhaling nor exhaling. The aligned relationship between the flap retaining surface and the seal surface and their relative positioning would not cause Simpson's flap 15 to be pressed against the valve's seal surface. At best the flap 15 would rest flush against the seal surface as a result of its securement at the flap retaining surface. The Simpson valve 13 therefore could allow for the influx of contaminants into the mask interior when, for example, a wearer tilts their head downwards and allows gravity to draw the flap away from the seal surface.²

Given the <u>aligned</u> relationship between Simpson's flap-retaining surface and its seal surface, there is no force or preload that would bias the flap to cause it to be pressed against the seal surface. As Simpson's FIG. 2 illustrates, the flap 15 on valve 13 would at best be in mere contact with the seal surface when a wearer is neither inhaling nor exhaling.

Thirdly, Simpson also fails to suggest the advantages that applicants' invention can provide. An invention's advantages must be considered under the "invention as whole" concept set forth in 35 USC § 103. Advantages that are not appreciated by the prior art provide very good evidence of nonobviousness.³ In the present case, applicants' invention possesses the benefit of achieving a low pressure drop value while preventing the influx of contaminants through the valve under any orientation. Simpson's valve, however, only protects to the wearer at the most critical time — during an inhalation. When a wearer of the Simpson mask inhales, the flap becomes firmly pressed against the seal surface. But when the wearer is neither inhaling nor exhaling, and has their head tilted downward, gravity can cause the flap to droop away from the seal surface. Simpson's valve may allow contaminants to enter the mask interior in this instance. To counter this problem, Simpson mounts the valve on the top of the mask body so that gravity can be used to keep the flap closed under neutral conditions. If the valve was mounted on the underside of

² A copy of the Bowers Declaration is attached to this Amendment.

See, e.g., In re Fine, 5 USPQ2d 1596, 1600 (Fcd. Cir. 1989) (Advantages not appreciated by prior art.).

Case No.: 48317US028

the mask, the flap would dangle away from the seal surface. The Simpson valve, unlike applicants' invention, therefore has limited suitable mounting positions on its mask body. But, even if it is mounted to the top of the mask body, it may still allow contaminants to enter the mask interior when the user fully tips their head downwardly. Unlike Simpson, however, applicants teach persons of ordinary skill how to make a low pressure drop flapper-style exhalation valve that will preclude contaminant influx under all orientations of the mask. This is achieved by the curved configuration of the flap and its being pressed against the seal surface under neutral conditions. Applicants' valve also does not have to be disposed on the top side of the mask. Applicants' invention, therefore, enables the valve to be disposed on the mask directly in the path of the exhale flow stream — that is, centered on the front of the mask — so that the valve can use the full momentum of the exhaled air stream to lift the flap from the seal surface. The failure of Simpson to appreciate these benefits and instead teach a more deficient construction further establishes the nonobviousness of applicants' invention. In short, Simpson does not teach the construction of applicants' valve, and it does not appreciate the benefits that that construction invention can provide. Under such circumstances, Simpson would not have rendered applicants' invention obvious to a person of ordinary skill within the meaning of 35 USC § 103.

Claims 34, 58, and 64 have been rejected as being obvious over Simpson in view of the French Patent 1,209,475. Applicants respectfully submit that this rejection cannot be sustained because (i) the French patent is not combinable with Simpson, and (ii) it is not analogous art.

In regard to item (i), the Examiner's attention is directed to *In re Lee*, 61 USPQ2d 1430 (Fed. Cir. 2002) ("The factual inquiry whether to combine references must be thorough and searching. It must be based on objective evidence of record. This precedent has been reinforced in myriad decisions, and cannot be dispensed with.") At the present time, the record is devoid of any evidence that Simpson's teachings could be combined with those of the French patent. Without such evidence, the obviousness rejection cannot be sustained. The record also does not provide any evidence that the requirements for showing that a reference is analogous have been met. In this regard, the Examiner's attention is directed to *In re Oetiker*, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992) ("In order to rely on a reference as a basis for rejection of the applicant's invention, the reference must either be in the field of the applicant's endeavor or, if not, then be reasonably

Case No.: 48317US028

pertinent to the particular problem with which the inventor was concerned."). Without any evidence to show that the French patent's high-pressure conduit valve is in the field of applicants' endeavor, namely, in the field of filtering face masks that use exhalation valves, and without any evidence that its disclosure would have been reasonably pertinent to the problems confronted by the applicant, the obviousness rejection, based on the French patent, cannot stand.

Claims 60-63 and 65 have been rejected under 35 USC § 103(a) as being unpatentable over Simpson in view of the French patent and U.S. Patent 4,934,362 to Braun. Applicants respectfully submit that these claims are patentable for the reasons presented above with respect to the rejections that apply Simpson with or without the French patent.

In regard to Braun, it teaches an exhalation valve that has its flexible flap mounted centrally in the valve. The flap has two free portions, one on which is disposed above the fixed portion of the flap. Rather than use a single flexible flap that has a non-centrally disposed stationary portion and only one free portion and a peripheral edge that includes a stationary segment and a free segment, where the free segment is disposed beneath the stationary segment when the mask is in its upright position when worn on a user, the Braun patent has its flap mounted centrally in the valve with free segments located both above and below the stationary or fixed portion of the flap. The Braun valve thus allows exhaled air to be directed upwards towards a wearer's eyeglasses, and it does not allow as great a moment arm to be achieved in lifting the flap from the seal surface. Applicants' invention can allow the flexible flap to be mounted towards one edge of the flap so that a greater distance can be provided between the free edge of the flap and its stationary portion. This allows the flap to open more easily in response to the exhale air flow. Because the Braun patent does not teach or suggest this beneficial structure, but instead describes a distinctly different structure that lacks these advantages, it also provides very good evidence that the present invention would not have been obvious to a person of ordinary skill under the meaning of 35 USC § 103.

U.S. Patent 3,191,618 to McKim also has been cited as a secondary reference against applicants' claims. As the Examiner is aware, this patent describes a curved seat reed valve. Its disclosure would not have contributed to the nonobviousness of the applicants' invention for a number of reasons.

Case No.: 48317U\$028

Firstly, the McKim patent cannot be cited against applicants under 35 USC § 103 because it too resides in a nonanalogous art. This fact has been established in the Castiglione, Bowers, and Fabin Declarations and Affidavits, copies of which are attached. Each of these documents shows that McKim does not reside in the field of applicants' endeavor, and McKim would not have been consulted for solutions to problems in designing exhalation valves for filtering face masks. As indicated above, the document must either be in the field of applicants' endeavor or be reasonably pertinent to the particular problem with which the applicant was concerned in order to qualify as citable prior art under 35 USC § 103.⁴ In order to be reasonably pertinent, the reference needs to be one that would have logically commended itself to an inventor's attention in considering the problem that confronted them.⁵

The record does not show that the McKim patent, which resides in the field of two-cycle engines, qualifies as also being in the field of filtering face masks that employ exhalation valves. McKim, therefore, does not satisfy the first prong for qualifying as being an analogous reference. Therefore, it is relevant to consider whether the McKim patent would have been reasonably pertinent to the particular problem that confronted the applicants. In the present case, the applicants were concerned with producing an exhalation valve that exhibited a lower airflow resistance in opening the valve. The applicants also sought to design a filtering face mask that would allow a greater percentage of exhaled air to be purged through the valve orifice. The record presently does not present any evidence that the McKim patent addresses these concerns. Instead, the McKim patent shows that it is directed to the problem of reducing float or bounce of its reed member. The need to reduce float or bounce in the valve of a two-cycle engine, however, is not a problem that concerned persons who design exhalation valves for filtering face masks.

Castiglione explained why persons of ordinary skill in his field do not consult reed valves for highspeed engines when developing exhalation valves for face masks:

⁴ In re Oeliker, 24 USPQ2d at 1445 (Fed. Cir. 1992).

⁵ In re Clay, 23 USPQ2d 1058, 1061 (Fed. Cir. 1992) ("A reference is reasonably pertinent if, even though it may be in a different field from that of the inventor's endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his problem. Thus, the purposes of both the invention and the prior art are important in determining whether the reference is reasonably pertinent to the problem the invention attempts to solve.").

Case No.: 48317US028

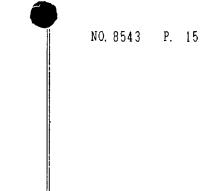
A filtering face mask is worn over the nose and mouth of a person for filtering contaminants that may be present in ambient air. Filtering face masks commonly employ exhalation valves to allow more moist exhaled air to be rapidly purged from the mask interior. The exhalation valves are used to improve wearer comfort. These valves operate at normal room temperatures and low pressures. The field of endeavor for a filtering face mask is very different from the field of endeavor of a curved seat reed valve that is used in a high-speed engine. Persons of ordinary skill in the field of designing filtering face masks do not consult documents that describe valves for gasoline engines in developing respiratory products. Exhalation valves for respirators operate under very different conditions from valves that are used in gasoline engines and require extraordinarily different design parameters.

[I]n exhalation valves for filtering face masks, the speed of opening is not a primary design parameter. There is no incumbent need to rapidly fill or exhaust a combustion chamber. Further, at the airflows and pressure drops that are encountered in a respiratory mask, "bounce" is not an occurring event. Investigators in the exhalation valve art for filtering face masks seek to produce exhaust valves that minimize force to open from the normally closed position. This particular design parameter is not compatible with fast-closing valves that require high forces for rapidly opening and closing. The flow volumes and flap stiffnesses are orders of magnitude higher for valves used in combustion engines as opposed to valves that are used on respiratory masks. For these reasons, a person of ordinary skill in the filtering face mask art would not have found the McKim patent to be reasonably pertinent to the problems that are encountered in the development of an exhalation valve for a filtering face mask.⁶

Also attached to this Amendment is a copy of Declaration signed by John Bowers, an inventor of an exhalation valve for Racal Health & Safety Limited (see U.S. Patent 5,687,767). Bowers states in paragraph 14 of his Declaration that McKim's goals of rapid opening, quick and complete closing, eliminating float or bounce have no pertinence to the operation of an exhalation valve where the opening and closing forces and speed with which the valve operates are on orders of magnitude different from the valve that is used in a two-stroke high-speed engine:

In exhalation valves for filtering face masks, the speeds for opening and closing is not a primary design parameter. There is no incumbent need to rapidly fill or exhaust a combustion chamber. Further, under the airflows and pressure drops that are encountered in a filtering face mask, "bounce or float" is not an occurring event or a problem that investigators in the exhalation valve art need to deal with. Investigators who design exhalation valves for filtering face masks seek to produce exhaust valves that remain closed between breaths and that minimize the

⁶ Castiglione Affidavit signed November 15, 1999 (copy of Affidavit is attached).



Case No.: 48317US028

force or pressure needed to open the valve from its normally closed position. This particular design goal is not compatible with or comparable to fast-closing valves that require high forces for rapidly opening and closing. Exhalation valves tend to open and close at the rate of a person's breathing, which is about 20 to 60 cycles per minute. In contrast, the McKim valve is designed to operate at speeds as high as 10,000 to 12,000 revolutions per minute. The flow volumes and flap stiffness are orders of magnitude higher for valves that are used in combustion engines as opposed to valves that are used on respiratory masks. For these reasons, a person of ordinary skill in the filtering face mask art would not, in my view, have found the McKim patent to be reasonably pertinent to the problems that are encountered in the development of an exhalation valve for a filtering face mask. McKim would not be a reference that would have logically commended itself to the attention of persons of ordinary skill in developing new exhalation valves for filtering face masks. I have not, nor have I witnessed, anyone who is skilled in the field of developing filtering face masks, look at the art of valves for two-cycle engines for solutions to problems confronted by them in the exhalation valve art.

This position is further supported by the attached Affidavit of Frank J. Fabin, a person who has been working in the field of occupational health for a number of years:

In my approximately 24 years of working in occupational health, I have not nor am I aware of another person who works in this field who has - consulted a reference in the reed valve art for gasoline engines to obtain solutions to problems encountered in developing exhalation valves that are used on filtering face masks,

In view of this testimony, it is clear that persons of ordinary skill in the exhalation valve art would not have consulted a reference to a reed valve for a two-cycle engine in developing an exhalation valve for a filtering face mask. McKim therefore is not a reference that would have logically commended itself to the attention of a person skilled in designing valves for filtering face masks. There is nothing in the record that indicates otherwise. McKirn therefore cannot be properly used as a reference against the present invention, whether combined with the Simpson patent or not.

Secondly, the Examiner is not correct in holding that McKim describes a flexible flap. As indicated in the attached Declaration of Richard Betts, a person skilled in the art of two-cycle engines, the McKim reed valve is not "flexible" as that term is defined in the present application:

Since 1965, the 2-cycle engines that I have either constructed or worked on have used a reed valve of varying degrees of stiffness. None of the reed valves that I have encountered, however, were "flexible" as the term has been defined in the abovecaptioned patent application and recited in paragraph 4 above. Reed valves that are used on 2-cycle engines can bend when exposed to a force such as shown in Fig. 3

OIPC 220 12W 01

Application No.: 09/680465

Case No.: 48317US028

of the McKim patent. The reed valves, however, are not so flexible that they will bend in the form of a self-supporting arc when secured at one end as a cantilever. Reed valves do not bend in the form of such an arc in response to the mere force of gravity. If the valves were constructed to have that degree of flexibility, the 2-cycle engines in which they were used would surely not be operative. If secured at one end as a cantilever and having a free end that projects from the point of securement, a reed valve would project in an essentially straight line when viewed from a side elevation. The degree of stiffness that reed valves possess are orders of magnitude greater than the flexible flaps that are used on exhalation valves.

Thus, it is improper to construe McKim's reed valve as being a flexible flap. As such, McKim even if analogous, does not describe the particular element for which has been relied upon in rejecting this application. The obviousness rejection, thus, cannot be properly sustained for this réason.

Thirdly, the record does not present any evidence that the disclosures in Simpson and McKim are combinable. As the Examine is aware, there must be some teaching or suggestion or knowledge generally available that would have led a person of ordinary skill to combine the pertinent disclosures in two separate documents.⁷ A probable reason why the record lacks any evidence that the McKim teachings are combinable with Simpson is because McKim is directed to a field entirely different from the field of exhalation valves for respirators.

McKim describes a curved seat reed valve that is designed for use in a two-cycle, highspeed engine which would turn at extremely high rpms — that is, at speeds as high as 10,000 or 12,000 revolutions per minute. This kind of technology would not be used by a person of ordinary skill in designing an exhalation valve for a respirator. McKim's valve is particularly suited for rapid operation where opening and closing forces are large. These forces can cause the valve to bounce (an elastic recoil from impact). The stated goals in McKim are full rapid-opening, quick and complete closing, and eliminating float or bounce. McKim's valve operates when a piston in the engine's cylinder moves from a top dead center to a bottom dead center, and the pressure within the crank case is reduced below atmospheric to overcome the spring bias of the valve reed. In

⁷ In re Fine at 1599 ("Obviousness is tested by 'what the combined teachings of the references would have suggested to those of ordinary skill in the art.' But it cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination.' And 'teachings of references can be combined only if there is some suggestion or incentive to do so.').

Case No.: 48317US028

attempting to give a reason why the references are combinable, the Examiner only states that "[i]t would have been obvious to modify the flexible valve flap and seat of Simpson et al. (fig. 2) to be curved because it would have provided quick seating, in an effective manner and without float or bounce after each opening as taught by McKim." The record, however, does not show that "float or bounce" problems are encountered in the exhalation valve art. The Examiner's position thus is merely broad conclusion unsupported by the record. The Federal Circuit has stated that such conclusions are not acceptable evidence for establishing a combination of references.8 Rather, the showing required to establish the combination "must be clear and particular". Although the record does not support the Examiner's position that McKim's search for a solution to the "rapid seating. float, and bounce issue for a 2-cycle engine" would be applied to an exhalation valve, it does show that this issue has no significance to persons who design exhalation valves. The Castiglione Affidavit and the Bowers Declaration establish this fact. This leaves the present record with nothing more than two isolated, unrelated disclosures. But the mere fact that it is possible to find two such disclosures, which might be combined in such a way as to produce a new mechanical device, does not render that device obvious. 10 Lacking such evidence, the combination cannot be properly sustained.

Thus, as the record presently stands, there is no evidence that McKim is analogous art, there is no evidence that McKim describes a flexible flap, and there is no evidence of any teaching or

⁸ In re Dembiczak, 50 USPQ 1614, 1617 (Fed. Cir. 1999) ("Broad conclusory statements regarding the teachings of multiple references, standing alone, are not 'evidence'.").

Id. ("The range of sources available, however, does not diminish the requirement for actual evidence. That is, the showing must be clear and particular."); see also Ruiz v. A.B. Chance Company, 57 USPQ2d 1161, 1168 (Fed. Cir. 2000) ("...the showing of combinability must be "clear and particular."); Brown and Williamson Tobacco Corp. v. Phillip Morrts Inc., 56 USPQ2d 1456, 1459 (Fed. Cir. 2000) ("However, the suggestion more often comes from the teachings of the pertinent references. This showing must be clear and particular, and broad conclusory statements about the teaching of multiple references, standing alone, are not 'evidence'."); and Winner Int'l Royalty Corp. v. Ching-Rong Wang, 53 USPQ 2d 1580, 1586-87 (Fed. Cir. 2000) ("Although a reference need not expressly teach that the disclosure contained therein should be combined with another, the showing of combinability, in whatever form, must nevertheless be 'clear and particular'.").

¹⁰ Smithkline Diagnostics Inc. v. Helena Labs Corp., 8 USPQ2d 1468 (Fcd. Cir. 1988) ("Merely pointing to a negative monitor in the prior art, which constitutes Helena's main argument to establish obviousness, is unpersuasive. Helena cannot pick and choose among the individual elements of assorted prior art references to recreate the claimed invention."); C.R. Bard Inc. v. M3 Sys. Inc., 48 USPQ2d 1225 (Fed. Cir. 1998) ("There must be something in the prior art as a whole to suggest the desirability, and thus the obviousness, of making the combination."); In re Grabiak, 226 USPQ 870 (Fed. Cir. 1985).

Case No.: 48317US028

suggestion to combine McKim with the Simpson patent. Therefore, the McKim reference adds nothing to what is lacking in the Simpson patent or any of the other "references".

For the above reasons, applicants urge the Examiner to favorably reconsider the rejections and allow this application at an early date.

Respectfully submitted,

April 26 , 2002

Date

Karl G. Hanson, Reg. Telephone No.: 651-736-7776

Office of Intellectual Property Counsel 3M Innovative Properties Company P.O. Box 33427 St. Paul, MN 55133-3427

Facsimile No.: 651-736-3833

Attachments: Affidavit of David M. Castiglione Declaration of Robert Betts Declaration of John L. Bowers Affidavit of Frank J. Fabin

Case No.: 48317US028

VERSION WITH MARKINGS TO SHOW CHANGES MADE

- 33. (amended) A filtering face mask that comprises:
- (a) a mask body that is adapted to fit over the nose and mouth of a wearer; and
- (b) an exhalation valve that is positioned on the mask body substantially opposite to a wearer's mouth, the exhalation valve comprising:
 - (1) a valve seat that comprises:
 - (i) a seal surface;
 - (ii) an orifice that is circumscribed by the seal surface; and
 - (iii) cross members that extend across the orifice to create a plurality of openings within the orifice; and
 - (2) a single flexible flap that has a fixed portion and [a] only one free portion and first and second opposing ends, the first end of the single flexible flap being associated with the fixed portion of the flap so as to remain at rest during an exhalation, and the second end being associated with the only one free portion of the flexible flap so as to be lifted away from the seal surface during an exhalation, the second end also being located below the first end when the filtering face mask is worn on a person, wherein the flexible flap would normally assume a flat configuration when not secured to the valve seat and having no forces are applied to it, but the flexible flap when secured to the valve seat at its fixed portion has a curved profile when viewed from a side elevation and is pressed towards the seal surface in an abutting relationship therewith when a fluid is not passing through the orifice.